Docket No. 17044 (AP)

PATENT

Serial No. 08/750,101

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Dolly, et al.	Examiner: Minnifield, N.
U.S. Serial No.: 08/750,101	Group/Art Unit: 1645
Filed: May 1, 1997	
For: MODIFICATION OF CLOSTRIDIAL TOXINS FOR USE AS TRANSPORT PROTEINS	

TRAVERSAL OF RESTRICTION REQUIREMENT AND AMENDMENT AND REPLY UNDER 37 CFR §1.119

Assistant Commissioner for Patents
Washington, D.C. 20231

Dear Sir:

This communication is in reply to the Office Action mailed March 23, 1998. Applicant has the following comments.

TRAVERSAL OF RESTRICTION REQUIREMENT

In a telephone conversation between the Examiner and Applicant's representative, the Examiner made a restriction requirement. Applicant's representative herewith affirms the provisional election of Examiner's Group I (claims 1-4, 7, 8, and 22-25), with traverse.

The Examiner has required restriction of Pending Claims 1-4, 7, 8, and 15-32 under 35 USC §§121 & 372. However, Applicant notes that the Examiner has applied PCT Rule 13.1 and 13.2 to the determination of whether restriction is required. Applicant notes that 35 USC §372 states that "all

CERTIFICATE OF MAILING

I hereby certify that this paper is being deposited with the United States Postal Service, first class mail in an envelope addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231.

Date: 7/23/98 By: Carlos A. Fisher
Carlos A. Fisher

questions of substance and, within the scope of the requirements of the Treaty and Regulations, procedure in an international application designating the United States shall be determined as in the case of national applications regularly filed in the Patent and Trademark Office." Accordingly, Applicant can find no stated grounds under 35 USC §121 for the restriction requirement made in the March 23, 1998 Office Action. Specifically, the Examiner has not indicated how any of the pending claims are independent and distinct, as required by 35 USC §121; without such indication, restriction may not properly be made (see MPEP § 803).

The Examiner has made two restriction groups; Group I includes Claims 1-4, 7, 8, and 22-25, said to be drawn to modified toxin (inactive), and pharmaceutical compositions and methods involving said inactive toxin. Examiner's Restriction Group II includes Claims 15-21 and 26-32, said to be drawn to a modified toxin (active), pharmaceutical compositions and methods of treatment including said active toxin.

In addition to the formal reason given above, Applicant respectfully submits that the restriction requirement is improper on substantive grounds. The Examiner must examine all the pending claims, even if distinctness or independence is shown, unless a serious burden would result from such examination. MPEP §803. However, a search of the art related to transport proteins made from modified inactive clostridial toxin, and pharmaceutical compositions and methods involving said inactive toxin would be expected to result in references concerning transport proteins made from the active toxin as well. The converse is also true. There is no indication that the two restriction groups represent inventions that have acquired a separate status in the art. Nor is there any evidence that the subjects of the two groups of claims have attained recognition in the art as separate subjects for inventive effort, thus resulting in separate classification. Thus, Applicant respectfully maintains that the Examiner has not established a *prima facie* case showing a serious burden to examine the claims together.

Even if the Examiner were to maintain the restriction requirement, Applicant notes that claim 15 is a linking claim, being generic to the species that the Examiner has indicated exist (i.e., transport proteins comprising clostridial toxins; inactive versus active). Claim 15 is a method claim encompassing both active and inactive clostridial neurotoxins, and therefore links the two restriction groups. As such, it should be examined with Group 1 and, if it is found patentable, the claims of Group II should be examined as well.